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10/560,933	06/14/2006	Giuseppe Zattera	82062-0187	4073

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EXAMINER	
PATEL, SHEFALI DILIP	
ART UNIT	**PAPER NUMBER**
3767	

NOTIFICATION DATE	DELIVERY MODE
03/11/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/560,933	ZATTERA, GIUSEPPE	
	Examiner	Art Unit	
	SHEFALI D. PATEL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,18-21 and 24-30* is/are pending in the application.

4a) Of the above claim(s) *27-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,18-21,24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgments

1. In the reply, filed on December 16, 2008, Applicant amended claims 1 and 24.

2. Applicant added new claims 25-30.

3. Applicant cancelled claims 22 and 23.

4. In the non-final rejection of August 22, 2008, Examiner objected to the Abstract for use of the terms "first and second occluding means". Applicant amended the Abstract to remove "means". Objection is withdrawn.

5. Examiner objected to claims 1 and 24 since "openings" [24] are used by two terms in the claims: "at least one opening" and "openings". To avoid confusion Examiner advised Applicant to use one consistent term within the claims. Applicant did not completely address this objection because claim 1 still contains "at least one opening" and "openings". Claim 24 was amended with "opening". Objection is maintained.

Election/Restrictions

6. Newly submitted claims 27-30 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: In the restriction requirement, of July 10, 2008, Examiner proposed an election between Group I (claims 1-15, 18-21, and 24, drawn to a catheter) and Group II (claims 22 and 23, drawn to the method for use of a catheter). In the reply, of July 30, 2008, Applicant elected Group I, without traverse. Examiner submitted an action on the merits for Group I on August 22, 2008. In the reply, Applicant added claims 27-

30 as new claims dependent upon claim 1 and 25 (catheter claims). Claims 27-30 parallel the restricted Group II claims 22 and 23 (method for use of a catheter). Hence, from the restriction requirement of July 10, 2008, claims 27-30 have already been shown to be a separate invention from claims 1-15, 18-21, and 24-26.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 27-30 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

7. Currently, claims 1-15, 18-21, and 24-26 are under examination.

Response to Arguments

8. Applicant's arguments with respect to claims 1-15, 18-21, and 24 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

9. Claims 1, 24, and 26 are objected to because of the following informalities:

In regards to claims 1 and 24, the openings [24] are used by two terms in the claims: "at least one opening" and "openings". To avoid confusion, one term should be consistently used within the claims.

In regards to claim 26, the preamble "The catheter of **C**laim 25" should be corrected "The catheter of **c**laim 25".

Appropriate correction is required.

10. Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

In regards to claim 9, the claims recites that the second occluding means comprises an occluding body and an insertion cable. Claim 9 depends upon claim 1. Claim 1 recites that the second occluding means contains an occluding body and an insertion cable. Claim 9 does not appear to further limit the subject matter of claim 1.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-7, 9-15, 18, 20, 21, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frazee et al (US 5,908,407), and further in view of Don Michael (US 5,163,905) and Petersen (US 3,490,457).

In regards to claims 1-3, 9, and 24-26, Frazee et al teaches a catheter (catheter [10]) for medical applications, suitable for being inserted into a duct comprising a first vessel (left transverse sinus [72] to right transverse sinus [74]) and a second vessel (superior sagittal sinus [56]) which branches off from said first vessel (Figure 8), the catheter [10] (Figure 4) comprising:

a. a catheter body (elongate tube [90]) which extends from a proximal end (proximal end [30]) to a distal end (distal end [32]), said catheter body [90] comprising a main cavity (through lumen [101]), bounded by a lateral wall, which passes through the catheter body [90] between the proximal end [30] and the distal end [32] (Figure 5)(column 4, lines 59-62), suitable for receiving a guide cable (guidewire [18]) for the insertion of the catheter into the first vessel (column 5, lines 20-28)(Figure 8), and at least one opening (ports [114][116][118]), disposed on the lateral wall at the distal end [32] and suitable for perfusing a substance (Figure 4)(column 5, lines 20-28), characterized in that the catheter body [90], at a portion of the lateral wall comprised between said at least one opening [114][116][118] and said distal end [32], comprises:

i. first (occlusion balloon [41]) (Figure 4) and second occluding means (septum valve [127]) (Figure 7), wherein the first occluding means [41] are suitable for at least partially occluding a gap between the catheter body [90] and an inner wall of the first vessel [72][74] (Figure 8), and the second occluding means [127] can be associated internally with said main cavity [101] and are suitable for at least partially occluding said main cavity (column 5, lines 29-31)

ii. said first [41] and second occluding means [127] defining a preferred direction of outflow (flow [62]) of a fluid from the main cavity [101] of the catheter body [90] to the second vessel [56], through said at least one opening [114][116][118] of the catheter body (Figure 8)

b. wherein all the openings [114][116][118] pass through said lateral wall and are in fluid communication with the main cavity [101] (column 5, lines 6-10)

c. said at least one opening [114][116][118] is such that the area of the at least one opening (Figure 4) is not less than the area of the cavity (at hole [125] of through lumen [101]) of the distal end [32] of the catheter body [90] (Figure 7)

Frazee et al does not teach that said openings [114][116][118] are not aligned with one another with respect to a main axis of extension of the catheter body [90], since Frazee et al teaches that said openings are aligned with each other with respect to the main axis of the catheter body (Figure 4). Don Michael teaches a catheter (catheter [2]) comprising openings (openings [28][30]), wherein said openings are not aligned with the main axis of the catheter, since said openings are disposed in a helical fashion about the catheter (Figure 2). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the catheter body of Frazee et al with non-aligned openings, as taught by Don Michael, as an obvious design choice to the user, since it has been held that rearranging parts (openings) of an invention involves only routine skill in the art. *In re Japikse, 86 USPQ 70.* Also, non-aligned openings will provide a wider area and direction of fluid flow, since the location of the openings is not restricted to one axis. Further, Frazee et al teaches that said second occluding means comprises an occluding body [127], suitable for being introduced into said main cavity [101]; however, Frazee et al does not teach that an insertion cable is firmly connected to said occluding body [127]. Petersen teaches a catheter (Figure 1) having a second occluding means comprising an occluding body (obturator tip [50]) and an insertion cable (handle [51]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the second occluding means, of the catheter of Frazee et al, with an insertion cable, as taught by Petersen, as the insertion cable will allow the user the ability to control the depth of the

occluding body within the catheter. *From Applicant's specification, the first occluding means is an inflatable element (page 8, lines 19-20), and the second occluding means is an occluding body and an insertion cable (page 9, lines 14-17).*

In regards to claim 4, in a modified catheter of Frazee et al, Don Michael, and Petersen, Frazee et al teaches that said first occluding means [41] comprises an inflatable element positioned round the catheter body [90] (Figure 4), said inflatable element [41], in a rest state, adhering substantially to the catheter body [90], and in a working state, being substantially in contact with the inner wall of the first vessel [72][74] (Figure 8) (column 3, lines 58-63).

In regards to claim 5, in a modified catheter of Frazee et al, Don Michael, and Petersen, Frazee et al teaches that said inflatable element [41] is in fluid communication with the proximal end [30] so as to be operable from said proximal end (column 4, lines 62-67).

In regards to claim 6, in a modified catheter of Frazee et al, Don Michael, and Petersen, Frazee et al teaches that said catheter body [90] comprises a secondary cavity (inflation lumen [105]), which extends from the proximal end [30] to the distal end [32] and is hermetically separated from said main cavity [101] (Figure 5), said secondary cavity [105] being in fluid connection with said first occluding means [41] so as to permit the actuation of said first occluding means (column 4, lines 59-67).

In regards to claim 7, in a modified catheter of Frazee et al, Don Michael, and Petersen, Frazee et al teaches that said secondary cavity [105] is produced in a thickness of said lateral wall of said catheter body [90] (Figure 5).

In regards to claims 10 and 11, in a modified catheter of Frazee et al, Don Michael, and Petersen, neither Frazee et al nor Petersen teach that the occluding body is substantially spherical or frustoconical in shape, since Frazee et al teaches that the occluding body [127] is cylindrical (Figure 7), and Petersen teaches that the occluding body [50] is conical (Figure 2)(column 3, lines 13-16). However, at the time the invention was made, it would have been an obvious matter of design choice to a person having ordinary skill in the art to modify the shape of the occluding body to be either spherical or frustoconical because Applicant has not disclosed that a spherical or frustoconical occluding body provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a cylindrical or conical occluding body because regardless of the shape of the occluding body, the occluding body will function to at least partially occlude the main cavity to minimize fluid flow towards the open distal end of the catheter.

In regards to claim 12, in a modified catheter of Frazee et al, Don Michael, and Petersen, Frazee et al teaches that said catheter body [90], at said distal end [32], comprises a portion with a tapered profile so as to reduce the cavity of the catheter body at the distal end (Figure 7).

In regards to claim 13, in a modified catheter of Frazee et al, Don Michael, and Petersen, Frazee et al teaches that said second occluding means, at said distal end [32], comprises a membrane [127] suitable for at least partially occluding said main cavity [101] and having a hole (slit [130]) suitable for allowing the passage of the guide cable [18] of the catheter (Figure 7) (column 5, lines 29-35).

In regards to claim 14, in a modified catheter of Frazee et al, Don Michael, and Petersen, Frazee et al teaches that said membrane [127] is firmly connected to the distal end [32] of the catheter body [90] (Figure 7) (column 5, lines 29-31).

In regards to claim 15, in a modified catheter of Frazee et al, Don Michael, and Petersen, Frazee et al does not state that the membrane [127] is made of a material suitable for being sterilized. However, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide a sterilizable material for the membrane, since it was known in the art, as common practice in the art, to sterilize medical equipment, such as catheters, in order to eliminate transmissable agents (bacteria, viruses, etc.) from medical surfaces in order to prevent contamination to the environment.

In regards to claim 18, in a modified catheter of Frazee et al, Don Michael, and Petersen, Frazee et al teaches a main pathway (connector [103]), at said proximal end [30], that is suitable for receiving said second occluding means [127] and is fluidly connected to said main cavity [101] (Figure 4) (column 4, lines 59-62).

In regards to claim 20, in a modified catheter of Frazee et al, Don Michael, and Petersen, Frazee et al teaches that said proximal end [30] comprises a secondary pathway (connector [107]), fluidly connected to said secondary pathway [105], and suitable for receiving at the inlet a fluid, so as to allow the flow of the fluid from the proximal end [30] to the distal end [32] (Figure 4) (column 4, lines 62-67).

In regards to claim 21, in a modified catheter of Frazee et al, Don Michael, and Petersen, Frazee et al teaches that said proximal end [30] comprises am infusion pathway (connector [103]), fluidly connected to said main cavity [101] and suitable for receiving at the inlet a fluid, so as to allow the flow of the fluid from the proximal end [30] to the distal end [32] (Figure 4) (column 4, lines 59-62)(column 5, lines 20-28).

13. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frazee et al, Don Michael et al, and Petersen, as applied to claim 6 or 7 above, and further in view of Prosl (US 5,868,717).

In regards to claim 8, in a modified catheter of Frazee et al, Don Michael, and Petersen, Frazee et al does not teach that said catheter body [90] has an oval cross-section with a first pole more pronounced than a second pole, since Frazee et al teaches that said catheter body has a circular cross-section (Figure 5). Prosl teaches a catheter [10] having an oval cross-section, wherein a first pole (second wall [30]) is more pronounced than a second pole (first wall [20] diametrically opposed to the first pole, and the first pole [30] receives the secondary cavity (second lumen [35]) (Figure 1B). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the cross-section of the catheter body, of the modified catheter of Frazee et al, Don Michael, and Petersen, with an oval cross-section, as taught by Prosl, as an obvious design choice to the user, since regardless of the cross-sectional shape of the catheter, the catheter will function to perfuse a substance into a vessel.

14. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frazee et al, Don Michael et al, and Petersen, as applied to claim 18 above, and further in view of Zhang (US 5,971,958).

In regards to claim 19, in a modified catheter of Frazee et al, Don Michael, and Petersen, Frazee et al does not teach that said main pathway [103] comprises a threaded section capable of producing a threaded connection with a corresponding threaded portion of said second occluding means [127]. Zhang teaches a catheter with a main pathway (introducer hub, *not referenced*) comprising a threaded section capable of producing a threaded connection with a corresponding threaded portion of a second occluding means (obturator, *not referenced*) (column 10, lines 23-65). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide a threaded section on the main pathway and a threaded portion on the second occluding means, of the modified catheter of Frazee et al, Don Michael, and Petersen, so that a threaded engagement, of the main pathway and the second occluding body, will inhibit the rotational disengagement of the main pathway and the second occluding body (column 10, lines 23-65).

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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